# EXHIBIT 25

# Morgan Lewis

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June 30, 2017

## CONFIDENTIAL TREATMENT REQUESTED

#### VIA HAND DELIVERY

Chairman Greg Walden Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, D.C. 20515

Ranking Member Frank Pallone, Jr. Committee on Energy and Commerce 2322A Rayburn House Office Building Washington, D.C. 20515

Chairman Tim Murphy
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Ranking Member Diana DeGette Subcommittee on Oversight and Investigations Committee on Energy and Commerce 2322A Rayburn House Office Building Washington, D.C. 20515

Congressman David B. McKinley Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, D.C. 20515

Dear Chairman Walden, Ranking Member Pallone, Chairman Murphy, Ranking Member DeGette, and Congressman McKinley:

I am writing on behalf of my client, AmerisourceBergen Drug Corporation ("ABDC"), in response to the Committee's letter dated May 8, 2017 regarding ABDC's distribution practices for certain opioid controlled substances sold into the State of West Virginia. ABDC shares the Committee's serious concerns about the opioid abuse crisis in the United States and the degree to which that crisis has impacted communities across West Virginia.

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In an effort to comply with all regulatory requirements, ensure a safe delivery system, and help address this crisis, ABDC has implemented rigorous anti-diversion policies and procedures and is actively engaged in various industry and policy group initiatives that support the fight against opioid abuse. For example, ABDC is a member of the Anti-Diversion Industry Working Group, which, working in conjunction with the National Association of Boards of Pharmacy, funded production of the red flags of diversion educational video used by numerous pharmacy boards, including the West Virginia Board of Pharmacy. Additionally, as part of the National Association of Drug Diversion Investigators, ABDC has presented on effectively combatting drug diversion at the distribution level and collaborating with law enforcement in that regard. ABDC is also the only distributor member of the Collaborative for Effective Prescription Opioid Policies. This collaborative consists of a group of representatives from patient and family advocacy, provider, public health, dispensing, distribution, and manufacturing organizations that support policies reducing prescription opioid abuse and promoting treatment options.

With regard to West Virginia in particular, ABDC has identified and reported to DEA and refused to ship over 800 suspicious orders for customers located within the State between 2008 and 2016. In fact, ABDC reported more suspicious orders to the DEA for West Virginia customers than for customers in all but four other states during that period. Moreover, it refused to service the pharmacy in Kermit, West Virginia, that the Committee references in its letter and was featured in the *Gazette-Mail* article.

Although ABDC is working hard to help deter diversion, its ability to address the broader problem is inherently limited by the role it plays as a single distributor in the market. In that role, it does not have visibility into a wide range of information that would be necessary to understand the overall supply chain for opioid products, including the opportunities for diversion within individual communities. For that reason, ABDC welcomes the Committee's attention to this issue and to the question of how best to ensure that the information flagged and shared by distributors is put to effective use to address diversion and help stem the current opioid crisis.

### ABDC'S ROLE IN THE DISTRIBUTION CHAIN

ABDC is a wholesale distributor of pharmaceutical products, including over-the-counter and prescription medications (both controlled and not), and other health-related products. Controlled substances comprise a very small percentage of all ABDC deliveries. Within West Virginia, for the period 2005 to 2016, solid oxycodone and hydrocodone dosage units accounted for only 2.1% of all ABDC prescription drug sales by dollar value and 3.9% of all prescription drug sales by dosage unit. As a wholesaler, ABDC purchases opioids from manufacturers and delivers them only to state-licensed and DEA-registered customers, including pharmacies, hospitals, and clinics. These shipments are made only pursuant to customer orders for opioids, which are dispensed when prescribed by duly licensed and registered physicians. ABDC reports to DEA's ARCOS database all sales of designated controlled substances, suspicious or not. Additionally, ABDC reports to DEA all orders it identifies as suspicious, as defined by the applicable regulation to include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. As noted above, ABDC has reported many hundreds of suspicious orders for customers within West Virginia.

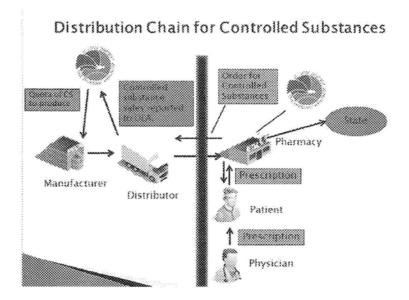
As a DEA-registered wholesale distributor, ABDC complies with all regulatory requirements<sup>1</sup> and is committed to the safe and efficient delivery of medications to meet legitimate patient needs across the United States. ABDC administers a robust anti-diversion program in order to meet, and in fact exceed, the requirements imposed on it as a distributor. ABDC's Order Monitoring Program ("OMP") is the means by which the Company monitors for suspicious orders of controlled substances and listed chemicals. The OMP is a multi-faceted approach to awareness, monitoring, investigation, and reporting overseen by ABDC Corporate Security and Regulatory Affairs ("CSRA"). ABDC's OMP exceeds all legal requirements.

As explained in more detail below, ABDC's anti-diversion program also includes, among other things, a "Know Your Customer" due diligence component. ABDC monitors its customers to identify other red flags indicators of diversion, such as a high percentage of controlled versus non-controlled substances purchased or an increased volume of high risk controlled substances ordered, that suggest additional investigation may be necessary. As a result of those efforts, ABDC has identified and maintains a list of pharmacies by DEA registration number to which no sales or shipments of controlled substances are to be made.

ABDC invests significantly in its effort to deter diversion, but there are unavoidable limits to ABDC's ability to monitor and prevent diversion given its defined role in the supply chain.

<sup>&</sup>lt;sup>1</sup> The requirements that the Controlled Substances Act ("CSA") impose on distributors within the closed opioid distribution system are relatively circumscribed. Distributors must obtain a DEA registration number to sell controlled substances in the United States, and the DEA imposes on them certain requirements as a condition of registration.

The only non-physical security requirements relevant to distributors are contained in § 1301.74. This section provides, in part, that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." Further, "[t]he registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." Suspicious orders are defined to "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." § 1301.74(b). Neither the CSA nor the implementing regulations prescribe any particular form of monitoring system identified in § 1301.74(b). The DEA leaves the design of the monitoring system to the distributor's sole discretion. Similarly, neither the regulations nor CSA provide any definition of "unusual" or "substantially" in the context of determining what constitutes a suspicious order.



ABDC has no control over, nor input into, the amount of controlled substances that are produced in a given year. Instead, production quotas are set by the DEA with input from manufacturers.<sup>2</sup> Nor is ABDC involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances. That responsibility belongs to federal and state governmental agencies, including the DEA. Finally, ABDC does not promote opioids to physicians, healthcare providers or patients.

#### ABDC'S EXTENSIVE DIVERSION CONTROL AND ORDER MONITORING PROGRAM

ABDC has had a program in place to monitor and report suspicious orders since at least the 1980s. Then, in 2007, an enhanced order monitoring program ("Legacy OMP") was created in consultation with DEA. The broader program consisted of policies and procedures dedicated to diversion control; a team of full-time diversion control employees; Know Your Customer Due Diligence; an Order Monitoring Program; ongoing monitoring and investigations; and training. As part of the Legacy OMP, certain criteria were established that would help in the identification of orders that varied in some significant way from the typical orders made by the customers of ABDC.

Although it had been reviewed and amended many times since its inception, beginning in 2014, ABDC undertook a comprehensive review of its Legacy OMP. The goal was to identify and implement improvements, while taking advantage of significant advancements in the use and efficacy of data-driven analytical tools. This culminated in the roll-out of an enhanced order monitoring program beginning in August 2015.

ABDC currently has 16 team members with responsibility for diversion control at the headquarters level and approximately 100 additional employees who have diversion control responsibilities across 26 different distribution centers. ABDC's Diversion Control Team, a team

ABDC's distribution of hydrocodone and oxycodone products are, of course, well below the DEA's annual production quotas, which apply to the production of all such products nationwide.

within CSRA, is led by David May, a retired career DEA agent who was the Assistant Special Agent in Charge of the Atlanta Field Office at the time of his retirement. Additionally, a Diversion Control Advisory Committee, made up of Senior Management and Legal Counsel, provides management input, support and oversight on diversion control activities as well as ensuring commitment to diversion control throughout ABDC.

ABDC has always provided training to the employees responsible for its order monitoring program. Some of that training has been formal training and some has been on-the-job training. In recent years, ABDC has moved to on-line training platforms to ensure consistency of training and the ability to track completion. ABDC has also added a test to the end of training for distribution center employees with order reviewing responsibility.

Below is additional information regarding the history and components of ABDC's New Customer Due Diligence and Order Monitoring Program, both of which serve as essential compliance controls to reduce the risk of diversion.

### NEW CUSTOMER DUE DILIGENCE

ABDC's New Customer Due Diligence is the process by which new customers are assessed for suitability in terms of ability to purchase controlled substances and listed chemicals from ABDC. Beginning in 2007, ABDC's New Customer Due Diligence of independent retail pharmacies generally required completion of ABDC's Retail Customer Questionnaire CSRA Form 590 ("Retail Customer Questionnaire"), which has been modified over the years. The information contained on the questionnaire is the basis for ABDC's due diligence investigation and provides a baseline to measure the pharmacy's ordering habits and to determine any deviation from expected purchasing practices. The questionnaire provides information to ABDC regarding anticipated ordering practices, including, among other things, the amount of controlled substances ordered, the anticipated ratio of controlled vs. non-controlled substances purchased, key prescribing doctors in the area utilizing the pharmacy, the purchasing practices of the pharmacy's customers (i.e. cash, credit, insurance, etc.), and whether another supplier is known to have suspended or ceased controlled substance sales to the customer. The questionnaire also includes inquiries on topics such as high-risk drugs and high-prescribing physicians. ABDC's due diligence investigation on potential retail pharmacy customers also includes verification of the pharmacy's DEA registration and state licensure; site visits; review of the pharmacy-provided information; and online investigation (including internet licensing and disciplinary searches) for identified pharmacy, owner, pharmacist-in-charge and any identified physicians. The questions on the questionnaire are based on guidance from the DEA.

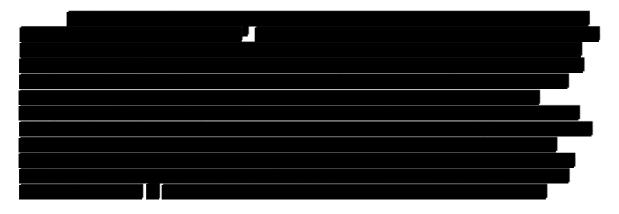
After ABDC receives the completed Retail Customer Questionnaire, it verifies that the prospective account was not listed on ABDC's "Do Not Ship List." That list provides a comprehensive record of all customers prohibited from purchasing controlled substances and listed chemicals from ABDC.

Additionally, completion of an updated standard checklist (CSRA Form 595) by each due diligence investigator is currently required when performing New Customer Due Diligence. The list helps ensure that the necessary review steps are completed, and documents compliance with those steps. Once the Retail Customer Questionnaire has been reviewed and investigated, the CSRA Form 595 completed, and the decision on whether to approve the pharmacy for purchase of controlled substances made, the file is sent to the Director of Diversion Control for final review and approval.

As noted above, ABDC rejected the Kermit, West Virginia pharmacy described in the *Gazette-Mail* article and the Committee's letter as part of the Company's New Customer Due Diligence. ABDC decided not to approve the pharmacy for the purchase of controlled substances and sent a rejection notice on May 5, 2009.<sup>3</sup>

#### ORDER MONITORING PROGRAM

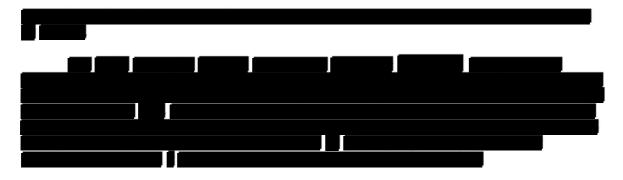
The Order Monitoring Program is the system designed by ABDC to meet its regulatory requirement to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The program has been enhanced over time to build on current data, trends in prescription drug abuse, and to leverage improved technological capabilities. Beginning in 2007, ABDC established a system to compare the purchases by pharmacies and hospitals against their peers to identify orders that were then held for additional review ("Orders of Interest"). If, based on that review, ABDC determined the order was of unusual size, deviated substantially from a normal pattern, or was of unusual frequency, the order was reported to DEA and was not shipped. In its current form, the Order Monitoring Program relies on a sophisticated algorithm to establish statistically-based parameters in order to identify Orders of Interest. To those orders, an objective process is applied to inform decisions on whether to refuse those orders and report them as suspicious.



In May 2009, Strosnider Drug, d.b.a. Sav-rite Pharmacy submitted paperwork for consideration by ABDC to be approved to purchase controlled substances. The New Customer Due Diligence performed on the customer revealed news reports indicating that the owner was under federal investigation for allegedly running a prescription drug ring.

For example, in May 2012, CSRA created a new drug family for oxycodone 30 mg immediate release formula, a formulation of the product that had been identified as particularly susceptible to abuse. The rationale was to rein in customers who primarily purchased the one strength of oxycodone while not punishing customers who had a more typical product mix.





Customer orders that exceed either (1)

, are not processed for shipment, but instead are held for review. The hold is electronic and, therefore, automatically blocks shipment until the review is complete and a decision is made as to whether to release the product for shipment.

Orders of Interest are first reviewed by trained personnel at the distribution center ("Responsible Person in Charge" or "RPIC"), who determine whether the order should be processed and shipped, rejected as a keying error, or escalated to CSRA for review and determination as to whether it is suspicious. All high risk product orders, except for those received from the Department of Defense, are escalated to CSRA. If the order is determined by the RPIC to present a risk of diversion, it continues to be blocked and the matter is elevated to CSRA for further analysis. When a keying error is confirmed, the RPIC rejects the order due to an administrative error, and the order is not reported. When the totality of the circumstances suggests no or low risk of diversion, the RPIC releases the order for processing and shipping.

CSRA has access to additional tools that the RPICs do not, including analytical dashboards and other reports that provide a broader perspective on customer ordering patterns, trends, and behaviors. They also have access to the customer's due diligence file, including the Retail Pharmacy Questionnaire. Following its review, CSRA can make one of three possible decisions: (1) reject and report to DEA as a suspicious order, (2) reject due to an administrative error, or (3) release and process for shipment. Again, no order reported as suspicious to DEA is shipped to the customer; every such order is cancelled and not shipped.

#### ADDITIONAL MONITORING

CSRA regularly reviews aggregated purchase data to identify concerning trends in purchases potentially missed in the review of flagged orders. CSRA uses various analytical dashboards and reports to facilitate the investigation of flagged orders and identify customers warranting further review. The dashboards and reports contain detailed customer order history as well as product and program activity and trends. They assist in identifying additional red flags for diversion such as a high percentage of controlled versus non-controlled substances purchased or an increased volume of high risk controlled substances ordered.

On-site customer investigations are triggered when specific issues or concerns come to the attention of CSRA through ongoing monitoring activities, the OMP, notifications from distribution center personnel, or inquiries from external bodies, including DEA or other enforcement agencies. ABDC partnered with The Pharma Compliance Group, a consulting group comprised of former DEA employees, to conduct some of those visits, alone or in conjunction with ABDC. The investigators

prepare comprehensive reports for use by CSRA in determining what, if any, action to take as a result of the visit.

#### LIMITS TO ABDC'S ABILITY TO PREVENT DIVERSION

As the Committee approaches the question of what additional legal requirements and controls can be established to address diversion, it is important to consider the limited information any distributor has regarding the overall market and supply chain for opioid products. As a distributor, ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information.

Due to strict medical privacy laws (including HIPAA), ABDC may not and does not review the prescriptions pursuant to which the pharmacies dispense opioids. Thus, it does not know the identities of the physicians that prescribe the opioids (unless voluntarily provided by its customers), the identities of the patients for whom the opioids are prescribed, how many pills have been prescribed for a patient, or whether any patient has obtained prescriptions from more than one doctor or filled prescriptions at more than one pharmacy. ABDC does not know the medical purpose for which any of the opioids are prescribed or whether the physician considered alternative therapies prior to prescribing. ABDC also has no opportunity to assess patient's ordering patterns or demeanor prior to dispensing. ABDC does not know where opioids go or how they are used after ABDC delivers them to its pharmacy customers.

As to its pharmacy customers, ABDC operates with a very narrow range of information. Unlike the DEA, unless voluntarily disclosed by its customers, ABDC does not know, nor may it due to antitrust concerns, whether its pharmacy customers buy opioids from other distributors or, if they do, what types or how many. And while all distributors must report certain information about their opioid sales – including suspicious orders of controlled substances – to the DEA, 21 C.F.R. § 1304.33. Only the DEA (i.e., not distributors) has access to that information across distributors.

In sum, drug wholesalers have a limited role in the supply chain, with limited access to information, and must rely on the other participants in the chain to do their part and comply with the regulations that apply to them.

Below are responses to the specific questions you have asked us to address. Please note that much of the information requested is addressed above in the body of this letter.

> Please provide the number of pills of hydrocodone and oxycodone sold by AmerisourceBergen to purchasers in West Virginia each year from 2005 through 2016.

**Response:** Below is a chart identifying the number of pills of hydrocodone and oxycodone distributed annually to West Virginia between 2005 - 2016.

	2005	2806	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Oxycodone												
Šelid	4,422,825	4,837,245	5,368,980	6,121,560	6,499,386	5,914,140	7,904,200	9,736,820	9,911,690	9,500,680	7,566,120	5,542,950
Hydrocodone												
Solid	11,268,240	13,191,910	14,979,930	16,227,850	17,637,630	10,896,400	12,043,080	12,968,260	10,254,690	10,390,630	8,289,540	5,972,580

For the period 2005 to 2016, oxycodone and hydrocodone pills accounted for only 3.9% of all prescription dosage units shipped by ABDC into West Virginia.

Please provide the names and addresses of your distribution centers that served West Virginia each year from 2005 through 2016.

**Response:** ABDC's distribution centers that served West Virginia from 2005 to 2016 include: Columbus, Ohio; Paducah, Kentucky; and Glen Allen, Virginia. Due to security concerns, ABDC can provide addresses in camera.

3. Does AmerisourceBergen have monitoring systems in place to detect unusual or suspicious patterns or quantities of opioid orders? If so, please describe those monitoring systems. Do your distribution centers that serve West Virginia have their own policies and systems for monitoring opioid orders, or do they follow or rely on your company's monitoring system?

**Response:** Please see above for a description of ABDC's monitoring systems used to detect orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. The distribution centers that serve West Virginia have the same policies and procedures as all other ABDC distribution centers for order monitoring.

4. What policies and procedures does AmerisourceBergen and/or your distribution centers that serve West Virginia have in place to take action in response to those detections, including notification of DEA and other authorities? Did your company or your distribution centers that serve West Virginia provide investigative leads to law enforcement authorities?

**Response:** Please see above for a description of ABDC's monitoring systems used to detect orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. As stated above, ABDC identified and reported to DEA and refused to ship over 800 suspicious orders for customers located in the State of

West Virginia between 2008 and 2016. In doing so, ABDC reported more suspicious orders to the DEA for West Virginia customers than for customers in all but four other states during this period. Additionally, it should be noted that the Suspicious Order regulation is an administrative reporting requirement; it does not constitute a complaint or an allegation of wrongdoing. After it submits a suspicious order report, ABDC does not have access to information regarding or visibility into what the DEA does to address the reports.

5. Did AmerisourceBergen and/or your distribution centers that serve West Virginia identify any patterns of opioid distribution in West Virginia that caused you to make a referral to the State Board of Pharmacy, DEA, or other authorities? If so, when did you become aware of those patterns?

**Response:** ABDC does not have access to sufficient information from which one might identify a "pattern" of opioid distribution—it has only information relating to its own sales and its own customers. The DEA has full information regarding all orders shipped by all distributors to each and every pharmacy in West Virginia, and the West Virginia Board of Pharmacy has full information on each and every prescription filled in West Virginia that is updated every 24 hours. Those two enforcement agencies have access to the broad information that might be able to present some sort of pattern; ABDC does not.

As set forth above, ABDC through its order monitoring program, identified and reported to the DEA over 800 suspicious orders for customers in the State of West Virginia between 2008 and 2016.

Please describe what actions were taken after identifying such patterns, including a timeline for these actions.

Response: Please see ABDC's response to Question 5.

7. If the reporting in the Gazette-Mail on opioid distribution to West Virginia is accurate, is AmerisourceBergen taking any specific action to examine its sales and monitoring processes in West Virginia and nationwide? If so, what actions have you taken to date and what additional actions are planned?

**Response:** ABDC believes that the reporting in the *Gazette-Mail* contained some accurate information but presented only one side of the story and lacked information to place the role of distributors in context. For example, ABDC refused to service the pharmacy in Kermit, West Virginia, that was featured in the article, as a result of its New Customer Due Diligence. Further, the articles did not explain that distributors

such as ABDC play no role in determining how much of each Schedule I and II Controlled Substance is needed to be manufactured to meet legitimate medical, scientific, and industrial need in the U. S. each year—the DEA sets those quotas; nor do distributors have any role in setting the legitimate demand for those substances which the DEA estimates in order to set the legitimate supply quota—the doctors and other medical practitioners who write the prescriptions in the "usual course of professional practice for a legitimate medical purpose" and the pharmacies who fill them do that. ABDC's role is to assure safe, timely, secure, efficient delivery of medications in response to valid orders from a licensed and registered pharmacy. ABDC never shipped any order to other than a duly DEA registered and West Virginia licensed pharmacy.

ABDC continually reviews and evaluates its diversion control program, which is implemented nationwide. With regard to West Virginia specifically, ABDC identified and reported to the DEA hundreds of suspicious orders.

8. Is there any data that DEA could share with your company, as appropriate given law enforcement and commercial confidential information sensitivities, that would help improve detection of suspicious orders of opioids?

**Response:** ABDC would welcome the opportunity to collaborate with the DEA and would welcome any data or criteria that the DEA considers of importance and that it believes might assist in identifying Suspicious Orders; for example, it could identify to ABDC pharmacies that, based upon its fulsome information, it suspects may be diverting, which would enable ABDC to apply a heightened level of monitoring to such pharmacies.

# CONFIDENTIALITY REQUEST FOR SENSITIVE INFORMATION IN THIS RESPONSE

The information shared with the Committee via this response is highly sensitive and would be detrimental to the public interest and could result in greater risks of opioid diversion, if disclosed. For example, if the operation of the compliance program were to be publicly disclosed, customers of ABDC would be more easily able to evade detection of potential diversion, thwarting the purpose of ABDC's compliance program. If a customer or potential customer seeking to divert were to learn the checks and balances put in place by ABDC, that customer may be more easily able to structure its purchases so as to avoid detection by the program, facilitating its diversion of controlled substances. Based on these risks and the proprietary and sensitive commercial nature of the programs and information disclosed herein, ABDC respectfully requests that this letter and the information contained herein be regarded as having been produced to the Committee in executive session and on a confidential basis. Should the Committee or any of its staff seek to release this letter or the

sensitive information contained herein to the public, ABDC requests advance notice so it can seek or petition for appropriate relief.

Sincerely

Matthew S. Miner